



PATENT APPLICATION

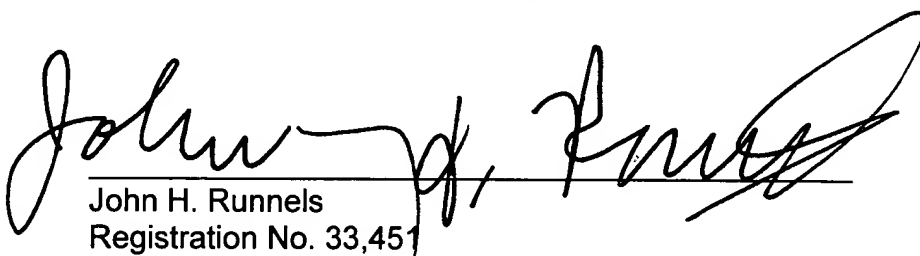
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Eugene A. Woltering *et al.* Group: 1651
Serial No.: 09/866,296 Examiner: Afremova, Vera
Filing Date: May 25, 2001
Title: Three-dimensional Ex Vivo Angiogenesis System
File No.: Woltering 98M06.1

CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that the listed enclosures are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 21, 2004.

- Reply Under 37 C.F.R. § 1.111
- Declaration of Eugene A. Woltering
- Fee Transmittal Sheet
- Check for \$110.00
- Return postcard verifying receipt of the listed enclosures


John H. Runnels
Registration No. 33,451

April 21, 2004

Eugene

1651\$



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Group 1651

Eugene A. Woltering *et al.*

Examiner Afremova, Vera

Serial No. 09/866,296

Filing Date May 25, 2001

For: Three-Dimensional *Ex Vivo* Angiogenesis System (File No. 98M06.1 Woltering)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY UNDER 37 C.F.R. § 1.111

Dear Sir:

This Reply is submitted in response to the Official Action dated January 13, 2004.

No further amendments are presented. Claims 1-10, 13, 38, and 39 remain pending in the application.

CERTIFICATE

I hereby certify that this Reply under 37 C.F.R. § 1.111 and the accompanying check for \$110.00 are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 21, 2004.

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John H. Runnels
John H. Runnels
Registration No. 33,451
April 21, 2004

Enclosed is a check for \$110 for a one-month extension of time, to extend the time for response from April 13, 2004 to May 13, 2004. (37 C.F.R. § 1.136(a)(3)). If this amount is incorrect, please refer to the Deposit Account Authorization previously filed for this application. If any additional extension of time is required, please consider this paper a petition for the total extension of time required.

The January 13, 2004 Office Action had the effect of withdrawing all prior grounds of rejection and objection, and of entering two new grounds of rejection.

Reexamination and reconsideration of the application are respectfully requested.

The § 112, First Paragraph Rejection

Claims 1-5, 7, 8, 10, 13, 38, and 39 were rejected on the ground that the specification "does not reasonably provide enablement for enabling for method of assaying angiogenic potential of a three-dimensional tumor embedded in collagen-containing matrix." (January 13, 2004 Office Action, p. 3)

As paragraphs 2-6 of the enclosed Declaration of inventor Dr. Eugene Woltering demonstrate, the method has been successfully demonstrated in a collagen-containing matrix, namely, one based on ECM gel. The experiments described in Dr. Woltering's Declaration were conducted in essentially the same manner as those reported in the original specification, except as noted, particularly the substitution of a collagen-containing system for the fibrin/thrombin clot system. Obtaining successful results with the collagen-based system was straightforward; undue experimentation was not required.

As Dr. Woltering's Declaration notes (Paragraphs 5, 6), the collagen-based system was less efficient than the fibrin/thrombin clot system. But more important is the fact that the collagen-based system did work, as the specification had correctly predicted.

It is respectfully submitted that the enablement ground of rejection should be withdrawn.

The §§ 102 and 103 Rejections

Claims 1-6, 9, 13, 38, and 39 were rejected under 35 U.S.C. §§ 102(a) and 103 as being anticipated by, or obvious over, the Gulec *et al.* paper, either taken alone or in combination with a secondary reference.

As paragraphs 7-10 of the enclosed Declaration of inventor Dr. Eugene Woltering demonstrate, the Gulec *et al.* paper represents a publication of the inventors' own work. Because the paper was published in May 2001, less than one year before the nearly-contemporaneous May 2001 filing date of the present application, the Gulec *et al.* paper has been removed as a reference.

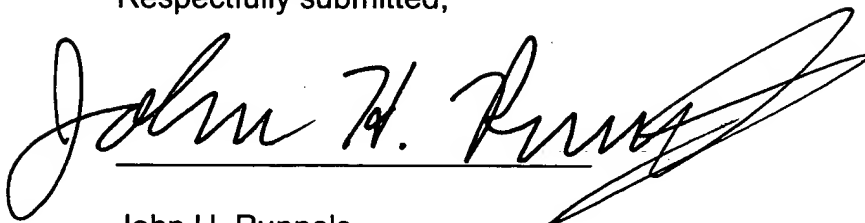
Applicants also note that the Gulec *et al.* paper was published after the May 2000 provisional filing date whose priority has been claimed under 35 U.S.C. § 119(e). While the provisional priority claim provides an additional basis to remove the Gulec *et al.* paper as a reference, it is not necessary to examine the disclosure of the priority application in detail to resolve this question. Even if one disregarded the effect of the priority application, the paper would still represent a publication of the Applicants' own work made less than one year prior to the filing date of the present application.

It is respectfully submitted that the Gulec *et al.* paper has been removed as a reference, that all prior art rejections have thereby been overcome, and that all §§ 102 and 103 rejections should therefore be withdrawn.

Conclusion

Allowance of Claims 1-10,13, 38, and 39 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "John H. Runnels", with a horizontal line drawn underneath the name.

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